IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation, Defendant.	)	Civil Action No. 02-1512-KAJ (Consolidated)
TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, TEVA PHARMACEUTICAL INDUSTRIES LIMITED, an Israeli corporation, and NOVOPHARM, LTD., a Canadian corporation, Counterclaim-Plaintiffs, v. ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Counterclaim-Defendants.	)	

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Plaintiffs, v. IMPAX LABORATORIES, INC., a Delaware corporation, Defendant.	Civil Action No. 03-120-KAJ (Consolidated)
IMPAX LABORATORIES, INC., a Delaware corporation, Counterclaim-Plaintiff v. ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATOIRES FOURNIER S.A., a French corporation, Counterclaim-Defendants.	
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Civil Action No. 05-340-KAJ (Consolidated)
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Civil Action No. 05-360-KAJ (Consolidated)

MEMORANDUM OPINION

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Wilmington, Delaware

TABLE OF CONTENTS

JORDAN, District Judge

I. INTRODUCTION

These antitrust actions have been brought by various plaintiffs[1] (collectively "Plaintiffs") against Abbott Laboratories ("Abbott"), and Fournier Industrie et Santé and Laboratoires Fournier S.A. (collectively "Fournier").[2] Before me is the Defendants' Consolidated Motion to Dismiss Plaintiffs' Complaints (C.A. No. 02-1512, Docket Item ["D.I."] 383, C.A. 02-1512, D.I. 429; C.A. 03-120, D.I. 294; C.A. 05-340, D.I. 38; C.A. 05-360, D.I. 39; the "Motion"). Jurisdiction is proper under 28 U.S.C. §§ 1331 and 1337. For the reasons that follow, I will deny the Motion.

II. BACKGROUND[3]

According to Plaintiffs, Abbott and Fournier have manipulated the statutory framework that regulates the market for pharmaceutical drugs in order to prevent generic substitutes for the branded drug TriCor® from having a meaningful opportunity

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[1]The actions have been brought by the following: Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") (*see* C.A. No. 02-1512, Docket Item ["D.I."] 360, Ex. A); Impax Laboratories, Inc. ("Impax") (*see* C.A. 03-120, D.I. 289); Walgreen Co., Eckerd Corp., The Kroger Co., Maxi Drug, Inc., Albertson's, Inc., Safeway, Inc., and Hy-Vee, Inc. (*see* C.A. 05-340, D.I. 31); CVS Pharmacy, Inc., Rite Aid Corp., and Rite Aid Hdqtrs. Corp. (*see* C.A. 05-340, D.I. 30); Pacificare Health Systems, Inc. ("Pacificare") (*see* C.A. 05-360, D.I. 35); the Putative Class of Direct Purchasers (the "Class of Direct Purchasers") (*see* C.A. 05-340, D.I. 29); and the Putative Class of Indirect Purchasers (the "Class of Indirect Purchasers") (*see* C.A. 05-360, D.I. 24). Novopharm, Ltd. ("Novopharm") was joined as a counterclaim-plaintiff in Civil Action No. 02-1512. (C.A. 02-1512, D.I. 426.) The plaintiffs in Civil Action 05-340 will be referred to collectively as the "Direct Purchasers," and those in Civil Action 05-360 will be referred to collectively as the "Indirect Purchasers."

[2]Abbott and Fournier will be referred to collectively as "Defendants."

[3]The following background information is based on Plaintiffs' allegations, which are assumed to be true for the purposes of this Rule 12(b)(6) motion.

to enter the market. (C.A. No. 02-1512, D.I. 360, Ex. A at ¶ 3.)[4] As context for those allegations, a description of the approval process for generic pharmaceutical drugs may be helpful.

A. *Generic Drugs and the Operation of the Hatch-Waxman Act*

Before a pharmaceutical drug is released into the market, it must be approved by the Food and Drug Administration ("FDA"), pursuant to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (D.I. 360, Ex. A at ¶ 32.) The manufacturer of a new branded drug must submit detailed safety and efficacy data for the drug to the FDA in a New Drug Application ("NDA"). 21 U.S.C. § 355(a). The NDA must also list "the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug." 21 U.S.C. § 355(b)(1). After approval, information about the branded drug, including patent information, is published by the FDA in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is generally called the "Orange Book," after the color of its cover. (*See* D.I. 360, Ex. A at ¶ 35.)

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), codified at 21 U.S.C. §§ 355, 360cc and 35 U.S.C. §§ 156, 271, 282, provides a framework for the introduction of generic versions of previously approved branded drugs. Under that framework, a generic manufacturer may submit

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[4]In support of the Motion, Defendants attack Plaintiffs' allegations without always distinguishing the plaintiff making a particular allegation. The several plaintiffs' allegations are similar, and, unless otherwise noted, common allegations will be referenced to Teva's counterclaims (C.A. 02-1512, D.I. 360, Ex. A). Also, unless otherwise noted, citations to the record refer to docket items in the case involving Teva, Civil Action 02-1512.

an Abbreviated New Drug Application ("ANDA") to the FDA. 21 U.S.C. § 355(j). (D.I. 360, Ex. A at ¶ 34.) The ANDA process allows the generic manufacturer to incorporate efficacy and safety data submitted to the FDA in the NDA for a branded drug, as long as the generic drug is shown to be bioequivalent to that branded drug. 21 U.S.C. § 355(j)(2)(A). (D.I. 360, Ex. A at ¶ 34.)

The Hatch-Waxman Act also provides a framework for the holders of pharmaceutical patents to enforce their patents against generic competitors. When filing an ANDA, a generic manufacturer must certify whether its generic drug will infringe any patents listed in the Orange Book as being associated with the branded drug. 21 U.S.C. § 355(j)(2)(A)(vii). (D.I. 360, Ex. A at ¶ 36.) For each listed patent, the ANDA applicant must make one of four possible certifications (respectively, the Paragraph I, II, III, and IV Certifications): (I) that no patent information on the branded drug has been submitted to the FDA; (II) that the patent has expired; (III) that the patent will expire on a stated date; or (IV) that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). A Paragraph I or II Certification poses no barrier to FDA approval, and one under Paragraph III allows approval after the patent expires. 21 U.S.C. § 355(j)(5)(B)(i)-(ii). A Paragraph IV Certification, however, makes the filing of an ANDA an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). Along with a Paragraph IV Certification, the applicant must provide notice to the patent holder of its invalidity or noninfringement position. 21 U.S.C. § 355(j)(2)(B)(i). The patent holder has forty-five days after receiving that notice to file a patent infringement suit. 21 U.S.C. § 355(j)(5)(B)(iii). Significantly, if an infringement suit is filed, FDA approval of

the ANDA is stayed until either thirty months have passed or a court rules that the patent is invalid or not infringed. *Id.* (*See* D.I. 360, Ex. A at ¶¶ 36-37.)

Pharmacists may dispense the generic equivalent for a branded drug when the branded drug is prescribed by a physician. (*Id.* at ¶ 77.) Such substitution is allowed, however, only if the generic drug has been "AB-rated" by the FDA, which means not only that the generic drug is bioequivalent to the branded drug, but also that the generic has the same form, dosage, and strength. (*Id.* at ¶ 78; C.A. 05-340, D.I. 29 at ¶¶ 41, 48, 81; C.A. 05-360, D.I. 24 at ¶¶ 27-28.) Therefore, an approved generic drug that is not AB-rated against a currently available branded drug, because, for example, the drugs have different formulations or dosages, may not be substituted for the branded drug and may only be sold, if at all, as a separately branded, rather than generic, drug. (D.I. 360, Ex. A at ¶ 78.)

B. *Defendants' Anticompetitive Conduct*

Defendants have allegedly manipulated the Hatch-Waxman framework in violation of the antitrust laws, in order to prevent generic substitution for their fenofibrate drug, TriCor. Fenofibrate is used to treat high levels of triglycerides, and also has indications for the treatment of high cholesterol. (*Id.* at ¶¶ 2, 44, 45.) Plaintiffs allege that Defendants responded to the threat of generic entry into the market by changing the formulation of TriCor, not to improve the product but simply to prevent generic formulations from becoming AB-rated for substitution with TriCor. Defendants changed the TriCor formulation twice: first, TriCor was changed from capsule form to tablet form, and second, it was changed from that initial tablet form to a second tablet form.

1. The Switch from Capsules to Tablets

Abbott has licensed from Fournier several patents covering fenofibrate formulations. (*Id.* at ¶ 21.) Abbott and Fournier are alleged to have worked together to procure patents and to market fenofibrate formulations under Abbott's TriCor brand name. In 1998, Abbott received FDA approval of its NDA for TriCor in capsule form. (*Id.* at ¶ 64.) That formulation was listed in the Orange Book, along with U.S. Patent No. 4,985,726 (the "'726 patent'"), which was asserted to cover that formulation. (*Id.*) In December 1999, Novopharm filed an ANDA for 67 mg and 200 mg fenofibrate capsules, along with a Paragraph IV Certification that its formulations did not infringe any valid or enforceable claim of the '726 patent. (*Id.* at ¶ 65.) In May 2000, Impax filed a similar ANDA. (C.A. 03-120, D.I. 289 at ¶ 30.) In response to those ANDA filings, Defendants filed lawsuits (the "Capsule Litigation") in the United States District Court for the Northern District of Illinois against Novopharm and Impax, in April and August 2000 respectively, alleging infringement of the '726 patent. (D.I. 360, Ex. A at ¶ 66; C.A. 03-120, D.I. 289 at ¶ 31.) By that time, Novopharm had been acquired by Teva.[5] (D.I. 360, Ex. A at ¶ 66.) The lawsuits triggered the thirty-month Hatch-Waxman stay of FDA approval of the generic formulations. (*Id.* at ¶ 66; C.A. 03-120, D.I. 289 at ¶ 31.)

In March 2002, the Northern District of Illinois granted summary judgment for Teva, holding that Teva's fenofibrate formulations did not infringe the '726 patent

[5]Teva does not make clear in its pleading how Novopharm was acquired. However it occurred, because of the acquisition and because Novopharm joins Teva's arguments as to this Motion (D.I. 431), I will refer to Teva and Novopharm collectively as "Teva" throughout this Memorandum Opinion.

because, in those formulations, fenofibrate was not comicronized with a solid surfactant, as required by the asserted claims of that patent. *Abbott Labs. v. Novopharm Ltd.*, No. 00-C-2141, 2002 WL 433584 (N.D. Ill. Mar. 20, 2002). The United States Court of Appeals for the Federal Circuit affirmed that judgment for Teva in March 2003. *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324 (Fed. Cir. 2003). The District Court then granted summary judgment for Impax, also in March 2003. (C.A. 03-120, D.I. 289 at ¶ 42.) According to the Direct Purchasers, Defendants knew that the accused formulations did not infringe and, therefore, had no probable cause to pursue the litigation against Teva and Impax. (C.A. 05-340, D.I. 29 at ¶¶ 120-23; C.A. 05-340, D.I. 30 at ¶¶ 76-79; C.A. 05-340, D.I. 31 at ¶¶ 80-83.)

While the Capsule Litigation was pending in the Northern District of Illinois, Abbott submitted an NDA for a new fenofibrate formulation: 54 mg and 160 mg tablets. (D.I. 360, Ex. A at ¶ 70.) That NDA was approved in September 2001, while the 30-month stay from the Capsule Litigation was still blocking approval of Teva's and Impax's ANDAs for fenofibrate capsules. (*Id.*) Defendants sought approval of a new indication for their tablet formulation, claiming that fenofibrate also could be used to increase levels of high density lipoprotein (HDL), or "good cholesterol." (*Id.* at ¶ 71.) To support the new indication, Defendants submitted data for the capsule formulation and argued that the new tablet formulation was bioequivalent to the capsule formulation. (*Id.*) According to Plaintiffs, Defendants' submission of the capsule data effectively admitted that the tablet formulation was not an improvement over the previous capsule formulation. (*Id.*)

After the NDA for the tablet formulation was approved, Defendants stopped selling TriCor capsules and also bought back the existing supplies of those capsules from pharmacies. (*Id.* at ¶ 70.) In addition, Defendants changed the code for TriCor capsules in the National Drug Data File ("NDDF") to "obsolete." (*Id.*) The NDDF is a private database that provides information about FDA-approved drugs. (C.A. 03-120, D.I. 289 at ¶ 23.) Changing the code to "obsolete" removed the TriCor capsule drug formulation from the NDDF, which prevented pharmacies from filling TriCor prescriptions with a generic capsule formulation. (D.I. 360, Ex. A at ¶¶ 73-74.)

Teva's ANDA for 200 mg capsules was approved on April 9, 2002, after the summary judgment in the Capsule Litigation caused the end of the Hatch-Waxman stay. (*Id.* at ¶ 68.) However, because the TriCor capsule formulation had already been removed from the market, generic substitution was no longer possible. (*Id.* at ¶¶ 77-78.) Teva has marketed fenofibrate capsules under the brand Lofibra®, but those sales have been modest. (*Id.* at ¶ 79.)

2. The Switch from Original Tablets to New Tablets

Because the only branded fenofibrate on the market was the TriCor tablet form, Teva and Impax each developed generic equivalents for that tablet formulation and submitted ANDAs for 54 mg and 160 mg tablets in June and September 2002 , respectively. (D.I. 360, Ex. A at ¶ 83; C.A. 03-120, D.I. 289 at ¶ 48.) With those ANDAs, Teva and Impax again submitted Paragraph IV Certifications stating that their formulations did not infringe any valid or enforceable patent claim listed in the Orange Book with Defendants' tablet formulation. (D.I. 360, Ex. A at ¶ 84; C.A. 03-120, D.I. 289 at ¶ 48.) In response to those ANDA filings, Defendants filed lawsuits in this court

against Teva and Impax, in October 2002 and January 2003 respectively, alleging infringement of the '726 patent, of U.S. Patent No. 6,074,670 (the "'670 patent"), and of U.S. Patent No. 6,277,405 (the "'405 patent"). (D.I. 360, Ex. A at ¶ 47; C.A. 03-120, D.I. 289 at ¶¶ 49-50.) Again, that triggered the thirty-month Hatch-Waxman stay. The current antitrust claims brought by Teva and Impax were set forth as counterclaims in that patent litigation.

Two other related patents were subsequently listed in the Orange Book for TriCor tablets: U.S. Patent No. 6,589,552 (the "'552 patent") in July 2003, and U.S. Patent No. 6,652,881 (the "'881 patent") in December 2003. (D.I. 360, Ex. A at ¶¶ 49, 53; C.A. 03-120, D.I. 289 at ¶¶ 51, 67.) Teva and Impax filed Paragraph IV Certifications as to those two patents, and, in response, Defendants filed successive patent infringement suits against Teva and Impax, first for the '552 patent and then for the '881 patent. (D.I. 360, Ex. A at ¶¶ 50, 51-52, 54-55; C.A. 03-120, D.I. 289 at ¶¶ 51-53, 68-69.) The lawsuits against Teva and Impax for the '726, the '670, the '405, the '552, and the '881 patents will be referred to collectively as the "Tablet Litigation." The '552 suit triggered an additional thirty-month stay, but, pursuant to a change in the statute that prevented successive litigation stays,[6] the '881 suit did not. (D.I. 360, Ex. A at ¶¶ 52, 55; C.A. 03-120, D.I. 289 at ¶¶ 53, 69.) Thus, the stay based on the first three patents was to expire in March 2005, and, absent an intervening court decision, the

[6]In 2003, the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(b), was amended to limit patentees to one thirty-month stay. *See* Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *IP and Antitrust* § 12.4c (2006) ("[L]egislative changes effective in 2004 deal effectively with the problem . . . by limiting patentees to a single 30-month stay for any given drug, regardless of the number of patents listed as covering that drug.").

additional stay based on the '552 patent was to expire in February 2006. (D.I. 360, Ex. A at ¶ 52.)

On May 6, 2005, I granted partial summary judgment for Teva and Impax, holding that their tablet formulations did not infringe the '552 patent. (D.I. 332; D.I. 360, Ex. A at ¶ 90.) Since that patent was the cause of the Hatch-Waxman stay extending beyond March 2005, Teva's ANDA was approved on May 13, 2005. Defendants then voluntarily dismissed their remaining infringement claims against Teva and Impax. (D.I. 360, Ex. A at ¶ 92.)

According to all Plaintiffs except for Impax, Defendants pursued the Tablet Litigation without probable cause because they knew that the patents-in-suit were rendered unenforceable by inequitable conduct before the U.S. Patent and Trademark Office ("PTO") and they also knew that the accused formulations did not infringe the patents-in-suit. (*Id.* at ¶¶ 212-26; C.A. 05-340, D.I. 29 at ¶¶ 120-23, 126-46; C.A. 05-340, D.I. 30 at ¶¶ 76-79, 82-102; C.A. 05-340, D.I. 31 at ¶¶ 80-83, 86-88, 92-109; C.A. 05-360, D.I. 24 at ¶¶ 81-85; C.A. 05-360, D.I. 35 at ¶¶ 62-64.) In addition, Teva alleges that the '881 patent was obtained through fraud on the PTO. (D.I. 360, Ex. A at ¶ 222.)

As before, while the Tablet Litigation was pending in this court, Defendants submitted an NDA for a new formulation, this time for tablets with a dosage of 145 mg and 48 mg instead of 160 mg and 54 mg. (*Id.* at ¶ 86.) For the new formulation, Defendants sought a label change stating that the new tablets no longer had to be taken with food (the "no food effect label" or "NFE label"). (*Id.* at ¶ 98.) However, according to Plaintiffs, that formulation was not an actual improvement over the previous tablets but was developed simply to prevent generic substitution. (*Id.*) As they

had done with the TriCor capsules, Defendants stopped selling the old TriCor tablets and changed the NDDF code to implement the formulation change to the new tablets. (*Id.* at ¶¶ 87, 90.)

C. *Plaintiffs' Legal Claims*

Based on the foregoing allegations, Teva makes ten claims (*id.* at ¶¶ 276-368): first, that Defendants have engaged in a conspiracy to monopolize the fenofibrate market, in violation of section 2 of the Sherman Act ("Section 2"), 15 U.S.C. § 2; second, that they have entered into a contract, combination, or conspiracy in restraint of trade, in violation of section 1 of the Sherman Act ("Section 1"), 15 U.S.C. § 1; third, that they have engaged in an overall scheme to monopolize the fenofibrate market, in violation of Section 2; fourth, that they have attempted to monopolize that market, in violation of Section 2; fifth, that they have entered into a contract, conspiracy, or combination to use sham litigation to restrain trade, in violation of Section 1; sixth, that they have engaged in sham litigation, in violation of Section 2; seventh, that they have listed patents in the Orange Book improperly, in violation of Section 2; eighth, that they have committed fraud during the prosecution of the '881 patent, in violation of Section 2; ninth, that Teva is entitled to injunctive relief in the form of a compulsory license of all patents listed in the Orange Book for the new tablet formulation; and, tenth, that Defendants have tortiously interfered with Teva's valid business expectancies

concerning the sale of fenofibrate.[7] Teva seeks treble damages and injunctive relief. (*Id.* at 95-96.)

Impax makes seven claims (C.A. 03-120, D.I. 289 at ¶¶ 144-74): first, that Defendants have entered into a conspiracy in restraint of trade, in violation of Section 1; second, that they have monopolized the fenofibrate market, in violation of Section 2; third, that they have attempted to monopolize that market, in violation of Section 2; fourth, that they have conspired to monopolize that market, in violation of Section 2; fifth, that they have engaged in a conspiracy to restrain trade, in violation of a California statute, Cal. Bus. & Prof. Code §§ 16720 et seq.; sixth, that they have engaged in an anticompetitive conspiracy, in violation of another California statute, Cal. Bus. & Prof. Code § 17200; and, seventh, that they have intentionally interfered with Impax's prospective economic advantage from the sale of fenofibrate.[8] Impax seeks treble damages and injunctive relief. (*Id.* at 36-37.)

The Direct Purchasers make two claims (C.A. 05-340, D.I. 29 at ¶¶ 160-84; C.A. 05-340, D.I. 30 at ¶¶ 115-27; C.A. 05-340, D.I. 31 at ¶¶ 123-36): first, that Defendants have monopolized the fenofibrate market, in violation of Section 2; and second, that they engaged in a contract, combination, or conspiracy to restrain trade, in violation of Section 1. The Direct Purchasers, like Teva and Impax, seek treble damages and

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[7]All of the Sherman Act claims include assertions that Teva is also entitled to relief under Section 4 of the Clayton Act, 15 U.S.C. § 15. (*See* D.I. 360, Ex. A at ¶¶ 286, 295, 305, 313, 323, 334, 343, 355.)

[8]As with Teva's claims, all of the Sherman Act claims in Impax's antitrust counterclaims are also asserted to be a basis for relief under Section 4 of the Clayton Act, 15 U.S.C. § 15. (*See* C.A. 03-120, D.I. 289 at ¶¶ 149, 154, 159, 165.)

injunctive relief. (C.A. 05-340, D.I. 29 at 65; C.A. 05-340, D.I. 30 at 40; C.A. 05-340, D.I. 31 at 41-42.)

The Class of Indirect Purchasers makes five claims (C.A. 05-360, D.I. 24 at ¶¶ 107-25): first, it seeks injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, for Defendants' alleged violations of Section 2; second, it claims that Defendants have violated the antitrust and consumer protection statutes of various states[9] and the District of Columbia; third, it claims that Defendants have been unjustly enriched by their unlawful conduct; fourth, it claims that Defendants have violated the Delaware Consumer Fraud Act, 6 *Del. Code* §§ 2511 et seq.; and fifth, it claims that Defendants have violated the consumer protection acts of every state and of the District of Columbia. The Class of Indirect Purchasers seeks treble damages and injunctive relief. (C.A. 05-360, D.I. 24 at 51.)

Pacificare makes three claims (C.A. 05-360, D.I. 35 at ¶¶ 180-209): first, it seeks injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, for Defendants' alleged violations of Section 2; second, it claims that Defendants have violated the antitrust laws of Arizona, California, and Nevada; and third, it claims that Defendants have violated the consumer fraud statutes of Arizona, California, Colorado, Nevada, Oklahoma, Oregon, Texas, and Washington, and have been unjustly enriched by their conduct. Pacificare seeks damages and injunctive relief. (C.A. 05-360, D.I. 35 at 44.)

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[9]Those states are Arizona, California, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin. (C.A. 05-360, D.I. 24 at ¶ 112.)

III. STANDARD OF REVIEW

Fed. R. Civ. P. 12(b)(6) requires a court to accept as true all material allegations of the complaint. *See Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts, Inc.*, 140 F.3d 478, 483 (3d Cir. 1998) (internal citation omitted). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set of facts consistent with the allegations of the complaint." *Id.* (internal citation omitted). The moving party has the burden of persuasion. *See Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991).

IV. DISCUSSION

In support of this Motion, Defendants argue (1) that, taking Plaintiffs' allegations as true, Defendants' conduct in changing the TriCor formulation and implementing those changes in the market does not violate federal antitrust law;[10] (2) that any actions taken in the Capsule and Tablet Litigations are immune under the antitrust laws because Plaintiffs have not adequately pleaded that those lawsuits were a sham; (3) that the overall scheme claims must be dismissed because the individual components of the scheme fail to state a claim; (4) that Plaintiffs have not pleaded antitrust injury for

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[10]In their arguments concerning antitrust liability, Defendants do not separately address the claims under different statutory sections, e.g., Section 1 or Section 2 of the Sherman Act. For example, while the cases that Defendants rely on discuss liability under Section 2, Defendants apparently intend their arguments concerning the legality of their conduct to apply equally to the Section 1 claims. (D.I. 384 at 17 ("For all these reasons, Plaintiffs' allegations relating to the introduction of new products and discontinuance of old products, do not state a claim under Section 1 or 2 of the Sherman Act.").) For purposes of this Motion, I will address Defendants' arguments as they have been framed, and I will not separately discuss the different statutory claims.

some of the claims; (5) that Plaintiffs have not adequately pleaded Abbott's or Fournier's involvement in portions of the alleged scheme; and (6) that the state law allegations fail to state a claim. Since each argument fails, the Motion to Dismiss will be denied.

A. *Antitrust Liability for Product Formulation Changes*

Defendants argue that their conduct in changing the TriCor formulation and implementing the change cannot support an antitrust claim. (D.I. 384 at 8-17.) First, they assert that Plaintiffs have conceded in their complaints that the TriCor formulation changes were improvements, and that any product change that introduces an improvement, however minor, is per se legal under the antitrust laws. (*Id.* at 8.) Thus, according to Defendants, the antitrust claims based on those formulation changes must be dismissed. Second, Defendants argue that they have not violated the antitrust laws because Teva and Impax have not been completely foreclosed from the fenofibrate market. Third, Defendants argue that they were not required to help their competitors, and so their withdrawal of old TriCor formulations and changes to the NDDF codes do not amount to antitrust violations. Those arguments both fail to state the proper legal standards and mischaracterize Plaintiffs' factual allegations

1. The Appropriate Standard

To violate Section 2, a monopolist's conduct "must harm the competitive process and thereby harm consumers. In contrast, harm to one or more competitors will not suffice." *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001). Thus, conduct must be examined to determine its anticompetitive effect, i.e., the effect on competition itself. *Id.* One of the benefits of competition is the introduction of new,

improved products. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286 (2d Cir. 1979) ("The attempt to develop superior products is . . . an essential element of lawful competition."); IIIA Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 781a (2d ed. 2002) (hereinafter "Areeda") ("[P]roduct superiority is one of the objects of competition . . . ."). Thus, while improved products may harm the sales of competitors, that harm is an aim and result of appropriate competition. *See* Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *IP and Antitrust* § 12.2 (2006) (hereinafter "IP & Antitrust") ("Innovation necessarily disadvantages rivals who do not keep up.").[11] Even a monopolist may "through technological innovation expand its market share, increase consumer brand identification, or create demand for new products," and such actions are "perfectly consistent with the competitive forces that the Sherman Act was intended to foster." *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 546 (9th Cir. 1983).

Because, speaking generally, innovation inflicts a natural and lawful harm on competitors, a court faces a difficult task when trying to distinguish harm that results from anticompetitive conduct from harm that results from innovative competition. "[T]he error costs of punishing technological change are rather high [and] . . . [c]ourts should not condemn a product change, therefore, unless they are relatively confident that the conduct in question is anticompetitive." IP & Antitrust § 12.1. If consumers are free to choose among products, then the success of a new product in the marketplace reflects consumer choice, and "antitrust should not intervene when an invention pleases

[11]I note that one of the authors of IP & Antitrust, Mark A. Lemley, represents Impax in this matter.

customers." Areeda ¶ 776d. If the new product is not successful, then there will be no significant injury to competitors and no need for antitrust intervention. *Id.* Based on those general principles, the Defendants argue that an antitrust claim premised on the introduction of new products must be supported by evidence that "the innovator knew before introducing the improvement into the market that it was absolutely no better than the prior version, and that the only purpose of the innovation was to eliminate the complementary product of a rival." (D.I. 384 at 10-11 (quoting Areeda ¶ 776d).)

That reasoning was applied in the *Berkey Photo* case, 603 F.2d 263, where the Second Circuit refused to weigh the benefits from Kodak's introduction of a new camera model and film format against the alleged harm from the product introduction, because that weighing had already occurred in the marketplace. 603 F.2d at 286-87. The fact that consumers bought Kodak's new products instead of those of its competitors accurately reflected the value of the new products, "so long as the free choice of consumers [was] preserved." *Id.* at 287. Thus, the Court concluded, the antitrust laws should not intervene. *See id.* ("If a monopolist's products gain acceptance in the market . . . it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion.").

A major logical underpinning of the Second Circuit's reluctance to inquire into the alleged anticompetitive effect of Kodak's new products was the success of those products in an open market, and the related conclusion that the harm to Kodak's competitors was a matter of consumer choice. *See* Areeda ¶ 781b ("[I]f buyers want it, is an antitrust court entitled to say that buyers should not have it? We doubt that the court has any choice but to accept consumer sovereignty, especially in the absence of

any criteria or calculus for deciding otherwise."). Consumers who are free to choose among various products enjoy the presence of competition rather than its absence.

By contrast, when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate. The court in *Berkey Photo* noted that consumers in that case were "not compelled" to purchase the new film, in part because "Kodak did not remove any other films from the market when it introduced the new one." 603 F.2d at 287. Indeed, "the situation [in that case] might be completely different if, upon introduction of the [new] system, Kodak had ceased producing film in the [old] size, thereby compelling camera purchasers to buy [the new] camera." *Id.* at 287 n.39. In the absence of free consumer choice, the basis for judicial deference is removed.

The D.C. Circuit in the *Microsoft* case, 253 F.3d 34, also recognized that "[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes" because such changes are part of competition. 253 F.3d at 65. Nevertheless, that court still concluded that "[j]udicial deference to product innovation . . . does not mean that a monopolist's product design decisions are per se lawful." *Id.* In that case, Microsoft's technological integration of its web browser and Windows operating system were subject to antitrust scrutiny, *id.* at 65-67, and the government was able to show that that integration had an anticompetitive effect, namely that it caused harm "not by making Microsoft's own [web] browser more attractive to consumers but, rather, by discouraging [the distribution of] rival products," *id.* at 65. Once the plaintiff demonstrated that anticompetitive effect, the burden shifted to Microsoft to present a procompetitive justification for its conduct. *Id.* at 59, 66-67.

The D.C. Circuit said that, if such a justification were offered, the plaintiff could rebut it or, alternatively, establish antitrust liability by demonstrating that "the anticompetitive harm of the conduct outweighs the procompetitive benefit." *Id.* at 59; *see also id.* at 67. That balancing approach embodies the familiar "rule of reason" test first articulated by the Supreme Court in *Standard Oil Co. v. United States*, 221 U.S. 1, 61-62 (1911). In the *Microsoft* case, Microsoft presented a procompetitive justification for only a portion of its technological integration, and was liable for the unjustified conduct. 253 F.3d at 66-67. As to the justified conduct, the government failed to rebut the procompetitive justification or show that it was outweighed by the anticompetitive harm, and so Microsoft was not liable under the Sherman Act. *Id.* at 67.

The nature of the pharmaceutical drug market, as described in Plaintiffs' allegations, persuades me that the rule of reason approach should be applied here as well. The per se standard proposed by Defendants presupposes an open market where the merits of any new product can be tested by unfettered consumer choice. But here, according to Plaintiffs, consumers were not presented with a choice between fenofibrate formulations. Instead, Defendants allegedly prevented such a choice by removing the old formulations from the market while introducing new formulations. Hence, an inquiry into the effect of Defendants' formulation changes, following the rule of reason approach, is justified. *Cf.* IP & Antitrust § 12.5 (inquiry as to product-switching conduct such as is alleged in this case is justified because that conduct "seems clearly to be an effort to game the rather intricate FDA rules to anticompetitive effect").

Therefore, in this case, an antitrust inquiry into the benefits provided by Defendants' product changes is appropriate. Contrary to Defendants' assertion, Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.[12] *See* 253 F.3d at 59, 66-67.

2. Plaintiffs' Allegations Relating to Product Innovation

In addition to their discussion of the legal standard, Defendants also assert that Plaintiffs have admitted that the new TriCor formulations had significant benefits, namely the new HDL indication for the first tablet formulation and the NFE benefit for the second tablet formulation. According to Defendants, those specific admissions are contrary to Plaintiffs' general allegations that the new formulations were not improvements. (D.I. 384 at 12-13.) Defendants err in two respects. First, as discussed above, Plaintiffs need not prove that the new formulations had absolutely no benefit. Second, the so-called admissions cited by Defendants only state that Defendants sought permission from the FDA to include the HDL indication and NFE label changes with the new formulations. Plaintiffs do not concede that those changes accurately reflected actual improvements in the drug. Indeed, they clearly make the opposite

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[12]I note the importance of the screening function that is carried out by the need for the antitrust plaintiff to show monopoly power. Only a manufacturer with monopoly power will be subject to the scrutiny under Section 2 discussed here. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 186 (3d Cir. 2005); *Microsoft*, 253 F.3d at 50-51. Defendants do not argue, for purposes of this Motion, that they lack the requisite monopoly power.

contention: that there were no significant medical benefits from the changes. (D.I. 360, Ex. A at ¶¶ 71, 86, 98; C.A. 03-120, D.I. 289 at ¶¶ 33, 59; C.A. 05-340, D.I. 29 at ¶¶ 80, 87-88, 108-09; C.A. 05-340, D.I. 30 at ¶¶ 50, 58-59, 104; C.A. 05-340, D.I. 31 at ¶¶ 51, 62-63, 111; C.A. 05-360, D.I. 24 at ¶¶ 53, 73, 93; C.A. 05-360, D.I. 35 at ¶¶ 47, 70.) Thus, Plaintiffs have made no concessions in this regard that would support dismissal of their claims.

3. Foreclosure from the Fenofibrate Market

Defendants next argue that their introduction of new fenofibrate formulations cannot be considered anticompetitive because it has not prevented Teva or Impax from selling fenofibrate. (D.I. 384 at 11-12.) Defendants are correct that, according to Plaintiffs' allegations, Teva and Impax have not been prevented from marketing the formulations that were the subject of their ANDAs, i.e., the old TriCor formulations. If it were true that an antitrust plaintiff had to show that competition were completely foreclosed, then Defendants' argument might have merit. However, that is not the correct legal standard.

To show that conduct has an anticompetitive effect, "it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005). Competitors need not be barred "from all means of distribution," if they are barred "from the cost-efficient ones." *Microsoft*, 253 F.3d at 64. Here, while Teva and Impax may be able to market their own branded versions of the old TriCor formulations, they cannot provide generic substitutes for the current TriCor formulation, which is alleged to be

their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.

4. Actions Taken to Support the Formulation Changes

Defendants assert (D.I. 384 at 14-17) that the actions they are alleged to have taken in support of the product changes, i.e., withdrawing the old formulations from the market and changing the NDDF codes, fail to support an antitrust claim because, according to Defendants, even a monopolist has "no general duty to aid competitors." (*Id.* at 14 (*citing Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004)).) Thus, while Defendants actions may have made it more difficult for Teva and Impax to compete, because those actions blocked generic substitution for TriCor, Defendants argue that they are not required to help Teva and Impax by allowing them to "free-ride on the TriCor brand." (D.I. 384 at 14-17.)

As discussed above, *supra* Section IV.A.1, while a monopolist may compete and is not required to aid its competitors, *see, e.g., Microsoft*, 253 F.3d at 58, "a monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior." *LePage's Inc. v. 3M*, 324 F.3d 141, 151-52 (3d Cir. 2003) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601-04 (1985)). Contrary to Defendants' assertion (D.I. 384 at 15), Plaintiffs allege harm to competition rather than simply harm to Teva and Impax. By removing the old products from the market and changing the NDDF code, Defendants allegedly suppressed competition by blocking the introduction

of generic fenofibrate. The Court in *Berkey Photo* noted that such conduct, which results in consumer coercion, is potentially anticompetitive. *See* 603 F.2d at 287 & n.39 (finding no liability but stating that "the situation might be completely different" if the defendant stopped producing old products or removed them from the market). Thus, the allegations of product removal and NDDF code changes, like the allegations related to the product changes themselves, support Plaintiffs' antitrust claims.[13]

As to the allegations regarding NDDF code changes, Defendants also assert that the changes were commercial speech protected under the First Amendment. (D.I. 384 at 16.) Even if the First Amendment applies, simply raising it as a talisman, as Defendants have done, is insufficient to provide immunity from antitrust scrutiny. The Supreme Court has addressed the issue of First Amendment protection from antitrust liability, stating that "First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972). Here, the changes in the NDDF code are alleged to be part of the Defendants' anticompetitive scheme, and those changes are an appropriate part of the circumstances to be considered in this case when evaluating Defendants' allegedly unlawful actions.

B. *Sham Litigation*

Plaintiffs allege that Defendants used patent infringement suits against Teva and Impax to block approval of those parties' ANDAs and prevent generic substitution for

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[13]Defendants also argue (D.I. 384 at 25-26) that Teva's claim that patents were wrongfully listed in the Orange Book (D.I. 360, Ex. A at ¶¶ 183-205, 335-43) must be dismissed. Teva has agreed to drop that claim. (D.I. 404 at 48 n.16.)

TriCor while Defendants were carrying out their product switching scheme. (*E.g.*, D.I. 360, Ex. A at ¶¶ 206-26.) A party that pursues litigation is generally immune from antitrust liability for that conduct, because such petitioning activity is protected by the First Amendment. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993) ("*PRE*"); *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136-37 (1961). The litigant will not be immune, however, if the litigation is a "sham." *PRE*, 508 U.S. at 56, 60. Accordingly, all the Plaintiffs, except for Impax,[14] also specifically allege that those lawsuits were sham litigation and, therefore, not immune from antitrust scrutiny. (D.I. 360, Ex. A at ¶¶ 212-26; C.A. 05-340, D.I. 29 at ¶¶ 120-23, 126-46; C.A. 05-340, D.I. 30 at ¶¶ 76-79, 82-102; C.A. 05-340, D.I. 31 at ¶¶ 80-83, 86-88, 92-109; C.A. 05-360, D.I. 24 at ¶¶ 81-85; C.A. 05-360, D.I. 35 at ¶¶ 62-64.) Specifically, those Plaintiffs allege that Defendants pursued those suits without a reasonable basis for claiming infringement (D.I. 360, Ex. A at ¶¶ 212-15; C.A. 05-340, D.I. 29 at ¶¶ 120-23, 126-28; C.A. 05-340, D.I. 30 at ¶¶ 76-79, 82-84; C.A. 05-340, D.I. 31 at ¶¶ 80-83, 86-88; C.A. 05-360, D.I. 24 at ¶ 85; C.A. 05-360, D.I. 35 at ¶ 64), and knowing that some of the patents asserted were unenforceable due to inequitable conduct before the PTO (D.I. 360, Ex. A at ¶¶ 218-22; C.A. 05-340, D.I. 29 at ¶¶ 129-46; C.A. 05-340, D.I. 30 at ¶¶ 85-102; C.A. 05-340, D.I. 31 at ¶¶ 92-109; C.A. 05-360, D.I. 24 at ¶¶ 83-84; C.A. 05-360, D.I. 35 at ¶ 63).

Litigation is a sham, and therefore not immune under the antitrust laws, if it satisfies a two-part test:

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[14]The pertinent allegations of Impax in support of its claim of an overall anticompetitive scheme are discussed separately, *infra* Section IV.C.

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor, through the use of the governmental *process*–as opposed to the *outcome* of that process–as an anticompetitive weapon.

PRE, 508 U.S. at 60-61 (internal quotation marks and citations omitted). Under that test, the intent of the parties in pursuing litigation is irrelevant unless the litigation is objectively unreasonable. *Id.* at 62. Objective reasonableness is equivalent in this context to the existence of probable cause to sue, and "[t]he existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." *Id.* "Probable cause . . . requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication." *Id.* at 62-63 (internal citation and quotation marks omitted).

According to Defendants, the undisputed facts demonstrate that they had probable cause to bring the four patent infringement suits against Teva and Impax based on the capsule and tablet ANDA filings. Accordingly, they assert that they are immune from antitrust liability for pursuing those suits. (D.I. 384 at 17-25.) Because the facts that Defendants point to do not demonstrate probable cause in the face of Plaintiffs' allegations, which I must accept as true in the context of this Motion to Dismiss, the sham litigation claims will not be dismissed.

1. Probable Cause for Alleging Infringement

For both sets of lawsuits, Defendants are alleged to have proceeded without a reasonable basis for asserting that the accused products infringed their patents. Teva, the Direct Purchasers, and the Indirect Purchasers all allege that Defendants pursued the Tablet Litigation without testing the accused generic products to determine whether they included the elements claimed by the asserted patent claims. As to the Capsule Litigation, the Direct Purchasers also allege that Defendants knew that their infringement position depended on an objectively unreasonable claim construction.

Defendants first argue (D.I. 384 at 20-21) that they were not required to carry out any particular testing of an accused product, so long as they did conduct "a good faith, informed comparison of the claims of [their] patent[s] against the accused subject matter." *Q-Pharma Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1302 (Fed. Cir. 2004). However, Plaintiffs' allegation is precisely that Defendants failed to carry out such a comparison. Thus, Defendants' assertion is contrary to the allegations, viewed in the light most favorable to Plaintiffs, and cannot support the Motion to Dismiss.

In response to the Direct Purchasers' allegation concerning the Capsule Litigation, Defendants contend (D.I. 384 at 24-25) that the mere fact that they lost those suits on summary judgment, because of a losing claim construction argument, does not demonstrate that they had no probable cause to make that argument. Indeed, they emphasize, "when the antitrust defendant has lost the underlying litigation, a court must resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." *PRE*, 508 U.S. at 60 n.5 (internal citation and quotation marks omitted).

However, while the fact that the Defendants lost may not be sufficient on its own to prove that the suit was baseless, neither does that fact contradict the Direct Purchasers' allegation that the suit was baseless. Defendants point to nothing in the published opinions that establishes as a matter of law that Defendants had probable cause to bring suit. Thus, those opinions, standing alone, provide no basis to dismiss the Direct Purchasers' claim.

2. Summary Judgment Opinion

As to the allegations based on the Tablet Litigation, Defendants argue that I may take judicial notice of the summary judgment opinion I issued, which, according to Defendants, demonstrates that there was probable cause to bring those suits. (D.I. 384 at 19-20.) However, Defendants point to nothing in that opinion that establishes as a matter of law that Defendants had probable cause to bring suit. Given Plaintiffs' allegations concerning the lack of a good faith infringement analysis and the knowing assertion of unenforceable patents, factual issues which are not addressed in the opinion relied on by Defendants, I will not dismiss the present claims at the pleading stage.

3. Inequitable Conduct

Again regarding the Tablet Litigation, Plaintiffs allege that Defendants knew that the patents-in-suit were unenforceable for inequitable conduct and, despite that knowledge, continued to pursue the litigation. Defendants respond, first, that inequitable conduct cannot be the basis for a sham litigation claim, and second, that Plaintiffs' allegations improperly depend on the subjective knowledge of Defendants

rather than the objective reasonableness of the patent infringement suits. (D.I. 384 at 21-23.) Both of those arguments fail.

First, in support of their argument that sham litigation may not be based on inequitable conduct, Defendants assert that the Supreme Court has specifically addressed the issue of antitrust liability arising from the enforcing of patents obtained by fraud. (*Id.* at 21-22.) In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 176-77 (1965), the Court held that the maintenance and enforcement of a patent obtained "by knowingly and willfully misrepresenting facts to the Patent Office" may be the basis of monopolization claims under Section 2. Because the Court in *Walker Process* required intentional fraud to form the basis for antitrust liability, *id.* at 177, Defendants reason that inequitable conduct alone, which covers a wider range of conduct, is not sufficient to support a *Walker Process* claim. *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.*, 812 F.2d 1381, 1384 (Fed. Cir. 1987). "Simply put, *Walker Process* fraud is a more serious offense than inequitable conduct." *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998). Thus, Defendants argue, allowing inequitable conduct to be the basis for a sham litigation claim, which would strip the antitrust immunity from Defendants' litigation conduct, would allow Plaintiffs to improperly circumvent the intentional fraud requirement set forth in *Walker Process*.

However, the conduct sufficient to show that Defendants had no reasonable basis to bring suit need not be the same as that required to support a *Walker Process* claim. In *PRE*, the Supreme Court noted, referring to *Walker Process*, that it was not deciding "whether and, if so, to what extent *Noerr* permits the imposition of antitrust

liability for a litigant's fraud or other misrepresentations." 508 U.S. at 61 n.6. According to the Federal Circuit[15]:

> *PRE* and *Walker Process* provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws; both legal theories may be applied to the same conduct. Moreover, we need not find a way to merge those decisions. Each provides its own basis for depriving a patent owner of immunity from the antitrust laws; either or both may be applicable to a particular party's conduct in obtaining and enforcing a patent. The Supreme Court saw no need to merge these separate lines of cases and neither do we.

Nobelpharma, 141 F.3d at 1071. For a sham litigation claim, "[i]n contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue. It is the bringing of the lawsuit that is subjectively and objectively baseless that must be proved." *Id*. at 1072. Therefore, contrary to Defendants' assertion, a sham litigation claim based on inequitable conduct is not an end-run around the requirements of *Walker Process*; it is, instead, a different claim, predicated on the objective and subjective reasonableness for bringing the lawsuit, rather than on the conduct before the Patent Office. Either theory may be used to overcome *Noerr* immunity.[16]

Defendants also argue that Plaintiffs' allegations of sham litigation are based on Defendants' subjective knowledge of inequitable conduct, which skips the necessary

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[15]"[W]hether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *Nobelpharma*, 141 F.3d at 1068.

[16]While the difference between *Walker Process* and sham litigation liability may be "somewhat elusive," Areeda ¶ 706a, at 187, a patentee might use a fraudulently obtained patent in an anticompetitive way without litigation, or conversely, the patentee may bring litigation that is objectively baseless for reasons other than fraud, including inequitable conduct. *Id*. at 187-88.

first step of examining whether the suits were objectively baseless. (D.I. 384 at 22-23.) That argument again mischaracterizes Plaintiffs' allegations, which state that any reasonable litigant in Defendants' position, knowing that the patents were unenforceable, would not have pursued the litigation. The objective prong of the *PRE* test requires an inquiry into the reasonableness of the belief that the litigation will be successful on the merits. *PRE*, 508 U.S. 60, 62-63. By contrast, the subjective prong of the test does not inquire into that belief, but looks rather at whether Defendants intended to use the litigation process to harm competitors. *Id.* at 60-61. Plaintiffs' allegations concerning the objective prong necessarily include the information about inequitable conduct that was available to Defendants when they decided to pursue the lawsuits. Contrary to Defendants' argument, those allegations relate to the objective reasonableness of pursuing those lawsuits and not solely to Defendants' subjective motivation.

Therefore, because the complaints adequately allege sham litigation, the Motion will be denied as to the sham litigation claims.

C. *Allegations of an Overall Scheme to Monopolize*

Defendants argue that Plaintiffs' allegations of an overall scheme to monopolize fail to state a claim, because, if liability is not found based on individual acts, then none can be found on the acts taken together. (D.I. 384 at 29.) That argument is contrary to the law. When determining antitrust liability based on a collection of factual allegations, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's*, 324 F.3d at 162 (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)); *see also City of Anaheim*

v. S. Cal. Edison Co., 955 F.2d 1373, 1376 (9th Cir. 1992) ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements."). Thus, Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not.

Defendants also argue that litigation conduct that is immune under *Noerr* cannot be included in the collection of facts used to support an overall scheme claim. (D.I. 384 at 29-30.) As discussed above, *supra* Section IV.B, the sham litigation allegations are sufficient to survive Defendants' Motion, so, for those plaintiffs that have alleged sham litigation, their allegations of an overall scheme properly include the litigation conduct. Thus, for Teva, the Direct Purchasers, and the Indirect Purchasers, the overall scheme allegations based on litigation conduct survive this Motion.

One plaintiff, Impax, has not alleged sham litigation. Impax argues, however, that even though that litigation may be immune under *Noerr,* it may still be relied on as part of a claim based on an overall scheme. (C.A. 03-120, D.I. 313 at 14.) To support that proposition, Impax, as well as Teva and Pacificare, cite several cases. (*Id.*; D.I. 404 at 34-36; C.A. 05-360, D.I. 69 at 28-29.) The primary source for the proposition that even good faith litigation may be considered as part of an overall scheme appears to be *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425 (10th Cir. 1952). In that case, the Tenth Circuit held that patent litigation, brought with the belief that patents were infringed, which "standing alone would not be sufficient to sustain a claim" under the antitrust laws, may still be "considered with [an] entire monopolistic scheme." *Id.*

That decision focused on the "real purpose" behind the litigation, which was "to further the existing monopoly and to eliminate [the other party] as a competitor." *Id.*

Three cases cited by Impax, Teva, and Pacificare mention *Kobe*. First, the Federal Circuit cited *Kobe* for the proposition that "patent owners may incur antitrust liability . . . where there is an overall scheme to use the patent to violate antitrust laws." *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576-77 (Fed. Cir. 1990). However, the court did not consider that theory or rely on it to support its decision to reverse the grant of a preliminary injunction; instead, the Federal Circuit merely cites *Kobe* in a list of possible bases for liability, without further discussion. Second, the Ninth Circuit recited the conclusion of *Kobe*, but it then went on to distinguish it. *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 994 (9th Cir. 1979). In the third case, a District Court in a passage of dicta cited *Kobe* to support its conclusion that evidence concerning litigation was admissible to prove an overall scheme. *ID Sec. Sys. Can., Inc. v. Checkpoint Sys., Inc.*, 249 F. Supp. 2d 622, 656 (E.D. Pa. 2003). Thus, *Atari*, *Handgards*, and *ID Security* support Plaintiffs' position only to the extent that they cite *Kobe*.

The other cases cited by Plaintiffs do not support their proposition that immunized litigation may be considered as part of an overall scheme. First, while the Supreme Court has stated, as quoted by Teva (D.I. 404 at 35), that "[i]t is well settled that First Amendment rights [e.g., the right to petition] are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute," *Cal. Motor Transp.*, 404 U.S. at 514, the Court went on to apply the *Noerr* standard and found that the complaint in that case stated a claim only after concluding

that the plaintiffs' allegations were "within the 'sham' exception in the *Noerr* case," *id*. at 516. Accordingly, that case does not support liability when the predicate litigation is not a sham. Finally, the decisions in *United States v. Singer Manufacturing Co.*, 374 U.S. 174, 194-95 (1963) and *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau*, 690 F.2d 1240, 1263-64 (9th Cir. 1982) state that an unlawful agreement, *Singer*, 374 U.S. at 194-95, or an unlawful overall scheme, *Clipper Exxpress*, 690 F.2d at 1263-64, do not become lawful because they may be enforced by immunized litigation. In other words, the immunized litigation does not immunize other conduct. *See Clipper Exxpress*, 690 F.2d at 1265 ("If [the plaintiff] can prove that the defendants engaged in activities which violated the antitrust laws, those violations do not become immune simply because the defendants used legal means . . . to enforce the violations.").

Thus, Plaintiffs' position ultimately depends on *Kobe* for support. However, the holding in *Kobe*, which predates *Noerr*, is contrary to more recent pronouncements by the Supreme Court concerning *Noerr* immunity. First, the Tenth Circuit's focus on the "real purpose" behind the litigation is contrary to the Supreme Court's holding in *PRE* that "only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation." 508 U.S. at 60. Second, and more fundamentally, the proposition that litigation with an objective basis may nevertheless be part of an overall scheme to monopolize is contrary to the Supreme Court's statement that such immunized conduct cannot form the basis for antitrust liability "either standing alone or as part of a broader scheme . . . ." *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965). The holding in *Kobe* must therefore yield to the Supreme Court's interpretation of *Noerr* immunity. That interpretation is also reflected in the

Federal Circuit's statement that "a patent owner who brings suit to enforce [a patent] is exempt from the antitrust laws, even though such a suit may have an anticompetitive effect, unless the infringement defendant proves . . . [*Walker Process* fraud or sham litigation]." *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000). No provision is made for liability predicated on immune litigation as part of an alleged overall scheme to violate antitrust laws.

Therefore, Plaintiffs may not use litigation conduct to support a claim of an overall scheme to monopolize if they cannot prove that the litigation was a sham.[17] On the current state of the pleadings, Impax, in particular, may not use Defendants' conduct in the Tablet Litigation because Impax fails to allege sham litigation. However, because Impax's other allegations unrelated to litigation survive this Motion, its overall scheme claim also survives based on those allegations.

D. *Antitrust Injury*

Antitrust plaintiffs not only must prove an antitrust violation, injury, and causation, they also must show that the injury they have sustained is an antitrust injury, "which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes [the] defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-*

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[17]If the antitrust plaintiff can prove the existence of sham litigation, the litigation conduct can be included in the mix of things alleged to violate the antitrust laws. If not, the antitrust claim can still be heard on the merits, but without the sham litigation allegations. In this way, courts avoid the risk of such mixed allegations being used as a subterfuge to avoid the stringent requirements of *Walker Process* or *Noerr* immunity.

IP & Antitrust § 11.4f.

Mat, 429 U.S. 477, 489 (1977). Antitrust injury "should reflect the anticompetitive effect either of the violation or of the anticompetitive acts made possible by the violation." *Id.*

1. *Walker Process* Claims

Defendants make two arguments concerning antitrust injury, one for the *Walker Process* claims and a second for the sham litigation claims. First, as to the *Walker Process* claims, Defendants argue (D.I. 384 at 27-29) that the claims based on *Walker Process* fraud for the '881 patent must be dismissed because adding that patent to the Tablet Litigation did not result in an additional thirty-month stay and, therefore, Plaintiffs have not adequately pleaded antitrust injury from the enforcement of the '881 patent alone. While that argument has superficial appeal, it fails on closer examination. The *Walker Process* claims are of two types. First, Plaintiffs each allege an overall scheme to monopolize that includes the fraudulent conduct. Second, Teva makes a separate Section 2 claim based on the fraud in procuring the '881 patent.

For the first type of claim, Defendants' argument fails because the presence of an antitrust injury must be determined after considering Defendants' conduct as a whole. As discussed above, *supra* Section IV.C, "the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's*, 324 F.3d at 162 (citing *Cont'l Ore*, 370 U.S. at 699). Since the claim depends on proof of the anticompetitive effect of the conduct as a whole, the question of antitrust injury should also be based on that conduct as a whole. *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 699-703 (E.D. Pa. 2004); *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 760 (D.N.J.

1999). Defendants do not argue that Plaintiffs have failed to allege antitrust injury for their overall scheme claims taken as a whole.

For Teva's separate *Walker Process* claim (D.I. 360, Ex. A at ¶¶ 344-55), Defendants' argument also fails, because in support of that claim, Teva has alleged that it was excluded from the fenofibrate market while the Tablet Litigation remained unresolved. The assertion made by Teva and Impax (C.A. 03-120, D.I. 313 at 5)[18] that the '881 litigation, based on a patent allegedly obtained by fraud, delayed resolution of the Tablet Litigation is consistent with those allegations.[19] Such exclusion from the market is "precisely the type of injury that the antitrust laws were intended to prevent," because it reflects an injury to competition. *Biovail*, 49 F. Supp. 2d at 772. Thus, Teva has adequately alleged antitrust injury for that claim as well.[20]

2. Sham Litigation Claims

Defendants' second argument concerning antitrust injury is that, assuming the '405 patent lawsuit was not a sham, Plaintiffs have failed to plead antitrust injury for the

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[18]That assertion, made by Impax in opposition to this Motion, is joined by Teva. (D.I. 404 at 2 n.1.)

[19]Attorneys' fees resulting from the addition of the '881 suit may also be an appropriate antitrust injury, although that proposition appears to be controversial. *Compare Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 543-46 (D.N.J. 2000) (fees may be antitrust injury) *with Brotech Corp. v. White Eagle Int'l Techs. Group, Inc.*, No. Civ.A.03-232, 2004 WL 1427136, at *6-*7 (E.D. Pa. June 21, 2004) (fees alone are not antitrust injury). Because the delayed market entry is sufficient injury, I need not decide, for purposes of this Motion, whether attorneys' fees are also an antitrust injury.

[20]Defendants argue (D.I. 384 at 28) that Impax has also failed to plead antitrust injury from a free-standing *Walker Process* claim, but, as Impax correctly points out (C.A. 03-120, D.I. 313 at 7), it does not make such a claim.

sham litigation claims based on the other lawsuits. (D.I. 384 at 29.) That argument fails because I have already concluded, *supra* Section IV.B, that the sham litigation claims, including those concerning the '405 patent, are not subject to dismissal at this stage.

E. *Allegations of Joint Conduct*

Plaintiffs' claims are directed at both Abbott and Fournier. Defendants argue (D.I. 384 at 31-38) that because some of those claims are only pleaded adequately as to one of the two Defendants, they must be dismissed as to the other. Defendants argue, first, that the pleadings are insufficient to support claims of *Walker Process* fraud and allegations of inequitable conduct against Abbott, and second, that the they are insufficient to support the product-switching claims against Fournier.

1. Allegations Against Abbott

Defendants are correct that the *Walker Process* and inequitable conduct allegations must be pleaded with particularity according to Federal Rule of Civil Procedure 9(b), because they are varieties of fraud. *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1358 (Fed. Cir. 2004) (*Walker Process* claims); *EMC Corp. v. Storage Tech. Corp.*, 921 F. Supp. 1261, 1263 (D. Del. 1996) (inequitable conduct claims). Rule 9(b) requires that "the circumstances constituting fraud or mistake shall be stated with particularity." Knowledge, however, "may be averred generally." Fed. R. Civ. P. 9(b).

Defendants do not argue that the allegations of Fournier's conduct before the PTO are insufficient to support the claims of fraud and inequitable conduct. Rather, they argue that nothing in those factual allegations implicates Abbott. (D.I. 384 at 32-

36.) It is true that a plaintiff "cannot sue multiple defendants for fraud merely by alleging fraud with particularity as to one defendant." *Sandvik AB v. Advent Int'l Corp.*, 83 F. Supp. 2d 442, 448 (D. Del. 1999). Thus, the complaints must allege Abbott's conduct with sufficient particularity to support the claims against it.

Plaintiffs' complaints are sufficient to support the *Walker Process* claims against Abbott. A *Walker Process* claim may be made against a party that knowingly enforces a patent procured by fraud on the PTO, even if that party did not itself prosecute the patent. *Walker Process*, 382 U.S. at 177 n.5; *Nobelpharma*, 141 F.3d at 1062, 1067-68. Thus, to adequately plead that claim, Plaintiffs must allege that Abbott knew that the '881 patent was obtained by fraud and still asserted that patent against Teva and Impax. Plaintiffs have done so. Indeed, they allege that Abbott and Fournier worked together in the prosecution of the fenofibrate patents, that Abbott knew that the '881 patent was obtained by fraud, and that an Abbott employee received from Fournier the technical report that allegedly was fraudulently withheld from the PTO. (D.I. 360, Ex. A at ¶¶ 105-82; C.A. 03-120, D.I. 289 at ¶¶ 73-103.) Abbott's knowledge, combined with its pursuit of litigation against Teva and Impax, is sufficient to support the *Walker Process* fraud allegations.

In support of their overall scheme claim, and in particular with respect to their sham litigation allegation, the Direct Purchasers allege that "Defendants were guilty of inequitable conduct in obtaining the '881 patent." (C.A. 05-340, D.I. 29 at ¶ 129; C.A. 05-340, D.I. 30 at ¶ 85; C.A. 05-340, D.I. 31 at ¶ 92.) Again, Defendants argue that no factual allegations in that complaint implicate Abbott because they all concern Fournier's conduct before the PTO. That is indeed the case. However, each of those

allegations also states that Defendants knew about the inequitable conduct (C.A. 05-340, D.I. 29 at ¶ 129; C.A. 05-340, D.I. 30 at ¶ 85; C.A. 05-340, D.I. 31 at ¶ 92), and each is made to support the contention that Defendants had no reasonable basis to bring and maintain the Tablet Litigation. (C.A. 05-340, D.I. 29 at ¶ 145-46; C.A. 05-340, D.I. 30 at ¶¶ 101-02; C.A. 05-340, D.I. 31 at ¶¶ 108-09.) Both Abbott and Fournier pursued that litigation, and the reasonableness of Abbott's belief in its merits is relevant, whether or not Abbott was directly communicating with the PTO. Thus, while the specific allegation that "Defendants were guilty of inequitable conduct in obtaining the '881 patent" must be understood as implicating only Fournier, that does not justify dismissing the claim against Abbott, because Abbott allegedly knew of the inequitable conduct, which in turn rendered the patents unenforceable and made enforcement efforts wrongful.[21]

2. Allegations Against Fournier

According to Defendants, the complaints show that the decisions concerning the changes in product formulations, the availability of old formulations, and the NDDF listing were made by Abbott. (D.I. 384 at 36-38.) However, Plaintiffs have alleged that Abbott and Fournier worked together in the alleged scheme of changing the fenofibrate

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[21]Abbott alternatively argues that the allegations be stricken pursuant to Rule 12(f) as to Abbott. (D.I. 384 at 36.) Rule 12(f) motions to strike are "not favored and usually will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties or if the allegations confuse the issues. . . . It is thus a drastic remedy to be resorted to only when required for the interests of justice." *Plaum v. Jefferson Pilot Fin. Ins. Co.*, No. Civ.A.04-4597, 2004 WL 2980415, at *2 (E.D. Pa. Dec. 22, 2004). For the *Walker Process* claim, the pleadings adequately support the claim and will not be stricken. I will also not strike the Direct Purchasers' inequitable conduct allegation, because it is fairly read to support the claim against Abbott.

formulations, obtaining patents covering those products, enforcing those patents against Teva and Impax, and ensuring that old formulations were no longer available for generic substitution. Contrary to Defendants' assertion, those are not "blanket" allegations that fail to meet the pleading requirements of Rule 8. (*Id.* at 37 (citing *Mountain View Pharm. v. Abbott Labs.*, 630 F.2d 1383, 1387-88 (10th Cir. 1980) (finding that pleadings that failed to give notice of which of 28 defendants were involved in conduct were inadequate)).) Thus, the claims against Fournier will not be dismissed.[22]

F. *State Law Claims*

Defendants briefly argue that the remaining claims for tortious interference, state law antitrust violations, and unfair competition and fraud violations must also be dismissed for failure to state a claim. Each of those arguments fails.

First, as to the tortious interference claims, Defendants argue that Plaintiffs must, in their complaints, identify specific relationships that have been disrupted. (D.I. 384 at 30-31.) However, Defendants provide no support for that contention, instead citing to cases where courts granted summary judgment because of a failure to prove the existence of any such relationships. (*Id.* at 31 (citing *Lucent Info. Mgmt. v. Lucent Techs.*, 5 F. Supp. 2d 238, 243 (D. Del. 1998); *Kirkwood Kin Corp. v. Dunkin' Donuts, Inc.*, No. 94C-03-189, 1995 WL 411319, at *9 (Del. Super. Ct. June 30, 1995)).) Contrary to Defendants' argument, it has been held in an antitrust case similar to this

[22]Fournier also moves alternatively for allegations to be stricken pursuant to Rule 12(f). Because the allegations support the antitrust claims against Fournier, I will not strike any of those allegations. *See supra* note 21.

that the "allegation that [the defendant] brought a sham patent infringement suit against [the plaintiff] with the purpose of keeping it out of the generic [drug] market [was] sufficient to state a claim for tortious interference with prospective business advantages." *SmithKline*, 383 F. Supp. 2d at 704. Therefore, the tortious interference claims will not be dismissed.

Second, as to the state law antitrust claims, Defendants assert that those claims "generally follow the standards and precedents of the federal antitrust laws and should be dismissed for the same reasons" as set forth for the federal claims. (D.I. 384 at 38.) Even if that assertion is correct, I have already concluded, *supra* Sections IV.A-IV.E, that the federal claims will not be dismissed, and so, for the same reasons, neither will the state law claims.

Third, for the unfair competition and fraud claims, Defendants argue that such claims "generally require some level of consumer deception or fraud," and that Plaintiffs have failed to allege fraud. (D.I. 384 at 38-39.) Defendants' general argument, with citations to decisions based on three of the fifty-one consumer protection laws asserted by Plaintiffs, fails to show that the claims should be dismissed. As the Indirect Purchasers note, under Delaware law, for example, the plaintiff need not prove all the elements of common law fraud. (C.A. 05-360, D.I. 70 at 23 (citing *Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983)).) Also, Plaintiffs have alleged that the NDDF codes were deceptively changed and that patents were obtained through fraud. Defendants have failed to demonstrate that such allegations are insufficient under any statute. Therefore, the claims will not be dismissed.

V. CONCLUSION

Accordingly, based on the foregoing reasons and authorities, I will deny the Consolidated Motion to Dismiss. An appropriate order will follow.